

**ASX Announcement**  
**27 October 2021**

**APPENDIX 4C**  
**QUARTERLY ACTIVITIES & CASHFLOW REPORT**  
**QUARTER ENDED 30 SEPTEMBER 2021**

**Melbourne, Australia, 27 October 2021:** Optiscan Imaging Limited (ASX: OIL) (**Optiscan** or the Company), a leader in medical technology using confocal laser endomicroscopy, is pleased to release its Appendix 4C – Quarterly Cashflow report and business update for the quarter ended 30 September 2021 (**Quarter**). All financial results are in Australian dollars and are unaudited.

**Highlights for the Quarter**

- **First Australian sale of a FIVE2 system to Swinburne University as part of a Victorian Government MedTechVic initiative.**
- **University of Melbourne’s Melbourne Dental School (MDS) trial to improve screening, diagnosis and treatment of oral cancer progressed with 110 imaging sets completed by the end of the Quarter and 120 sets by 20 October.**
- **Australia’s 2nd highest ranked dental school, the University of Adelaide Dental School, received final approval for its “Proof of Concept Study: A diagnostic tool to detect Oral Squamous Cell Carcinoma”.**
- **Progress continues in preparing for the application for FDA approval for the InVivage™ device for use in oral cancer screening and surgery in the United States.**
- **Completed imaging of 35 of 40 patients for stage three of the Breast Cancer Surgical Margin Assessment Trial.**
- **Increased sales pipeline for FIVE2 system with funding applications for purchases made and demonstrations conducted in Australia and North America.**
- **Orders from Carl Zeiss Meditec AG (CZM) for the CONVIVO device of approximately \$175k for use in neurosurgery.**
- **Total Cash Flows of (\$844k) for the Quarter with Cash Flows from Operating Activities of (\$935k) for the Quarter ending 30 September 2021.**

**Developments Post End of Quarter**

- **A leading Melbourne based medical research institution has received funding approval for a FIVE2 system and purchase documentation is being prepared. This will be the second Australian sale of a FIVE2 system this financial year.**
- **Receipt of Optiscan’s R&D Tax Incentive rebate for the 2020/21 financial year amounting to \$770k. The R&D Tax Incentive is an Australian Government program under which companies receive cash refunds for 43.5% of eligible expenditure on research and development.**

## **Oral Cancer Surgery and Screening Application – InVivage™**

### **Oral Cancer Trial at Melbourne Dental School**

The Melbourne Dental School (MDS) trial to improve screening, diagnosis, and treatment of oral cancer continued in the September 2021 quarter with a further 51 imaging sets completed during the Quarter. This takes the total number of screening sets since the trial began in September 2020 to 110 and 120 sets by 20 October 2021.

Patient recruitment was impacted by increased COVID restrictions in hospitals which has slowed the rate of imaging. Increased vaccination rates and the removal of various travel and other restrictions are expected to significantly increase the rate of imaging.

### **Other Oral Cancer Trials and Studies**

During the Quarter, Australia's 2<sup>nd</sup> highest ranked dental school, the University of Adelaide Dental School, received final approval for its "Proof of Concept Study: A diagnostic tool to detect Oral Squamous Cell Carcinoma". This 30 patient ex vivo study will use Optiscan's FIVE2 (ViewnVivo) system for applications in relation to oral and oropharyngeal cancer. Use of Optiscan's technology by another leading Australian dental school will be an important validation of its efficacy and utility as Optiscan moves closer to approval and commercialisation of its clinical device. Following the end of the Quarter, a system has been sent to the Adelaide Dental School for the conduct of the study.

Discussions took place with a leading Melbourne based oral surgeon regarding the commencement of an oral cancer surgical clinical trial at one of Melbourne's most highly regarded hospitals and are expected to be advanced following the lifting of COVID restrictions.

## **Preparations for seeking United States Food and Drug Administration (FDA) approval for the InVivage™ device in the United States**

During the Quarter, Optiscan continued to progress preparing for its application for 510(k) clearance to market the InVivage™ clinical device for use in human oral cancer screening and surgery in the United States.

Optiscan has been working closely with United States based independent contract testing laboratories for medical devices and pharmaceuticals to progress various cleaning, disinfection, electrical and laser safety tests. The nature of these tests means they involve various stages and iterations. During the Quarter, internal validation and verification procedures continued, including life testing the new build of the probe and of the system.

Development of the strategy for the InVivage's market entry strategy into the United States continues, with the objective of having a clear pathway to commercialisation when FDA approval is received. A branding specialist was engaged to develop the InVivage branding strategy, and Optiscan continues to work with a former leading medical executive and oral surgeon to assist in all aspects of the market entry strategy. The United States market entry strategy for InVivage™ is supported by funding from Federal Government Entrepreneurs' Programme Growth Grant.

## **Breast Cancer Surgical Margin Assessment Trial (Breast Trial)**

The Breast Cancer Intraoperative Assessment Trial (ex vivo study) at Royal Melbourne, Frances Perry and Epworth Hospitals continued during the Quarter. In July, the breast trial was extended from 20 patients to 40 patients, due to strong patient interest in participating in the study. 15 additional patients were imaged during the Quarter with a total of 37 patients now imaged. Recruitment of new patients has been delayed in recent months due to COVID restrictions at the Royal Melbourne Hospital, however, these restrictions have now been relaxed and recruitment can continue at all three hospitals. Imaging of all 40 patients is expected to be completed in the next few weeks.

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## **NeuroSurgery – CONVIVO - Carl Zeiss Meditec Collaboration**

The collaboration with Carl Zeiss Meditec AG (CZM) in neurosurgery continues with orders for the CONVIVO device of approximately \$175k during the Quarter.

## **FIVE2 (ViewnVivo) Distribution**

The Company continued to develop its sales pipeline and distribution arrangements for the FIVE2 system both in Australia and offshore. Universities, cancer centres and other research institutions are interested in the FIVE2 device for a range of applications including pure research, veterinary science and for exploration of new clinical applications of the technology.

The first Australian sale was recorded in the Quarter to Swinburne University as part of a Victorian Government MedTech initiative. The system was delivered in September and the tissue culture research collaboration between the Company and Swinburne has commenced.

During the Quarter, a number of discussions and demonstrations were held with highly regarded Australian medical research institutions and hospitals including Walter and Eliza Hall (WEHI), Monash University, Melbourne University, Peter MacCallum Cancer Centre and the Children's Medical Research Institute in Sydney.

In Europe, a system was delivered to the University of Bergen in Norway who have already reported pleasing imaging results in relation to health monitoring of live fish in aquaculture.

Activity in North America is gaining momentum with several discussions and virtual demonstrations with leading universities and hospitals including Johns Hopkins University, Memorial Sloan Kettering Cancer Centre (separate to the existing oral application), UC Davis and Roswell Park. Similar activities are being planned with a leading US-based pharmaceutical company.

## **COVID-19 update**

The Company continues to maintain a COVID-19 safe working environment. Optiscan has adjusted well to conducting presentations and demonstrations remotely and is closely managing its customers and suppliers throughout the COVID-19 pandemic. As we approach the end of calendar year 2021 and Australia's internal and international borders open, Optiscan is confident of being able to resume live demonstrations interstate and in select offshore countries.

## **Corporate Update and Outlook**

The Company received funds of \$141k pursuant to the exercise of options during the Quarter.

Research and development costs during the quarter amounted to \$578k, including \$111k paid to the MDS received from the BioMedtech Horizons grant. The Company incurred \$261k in manufacturing and operating costs.

Following the end of the Quarter, the Company received \$770k in respect of the R&D Tax Incentive rebate for the 2020/21 financial year and expects to receive the balance of the sale proceeds from the Swinburne sale and the funds from the second Australian sale in the current quarter.

All related party payments noted in Section 6 of the accompanying Appendix 4C during the Quarter relate to payment of executive and non-executive director's fees and salaries.

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This announcement has been authorised for release by the Board of Optiscan.

**For investor queries, please contact:**

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**About Optiscan**

Optiscan is a global leader in the development of microscopic imaging and related technologies for surgery and medical research. Based in Victoria, Australia, Optiscan was established in 1994, and listed on the ASX in 1997 (ASX: OIL). Optiscan has developed and patented endomicroscopic technology which enables real-time, 3D, 'in vivo' imaging of human tissue at the cellular level for cancer screening, diagnoses and in surgery.

**Disclaimer**

*All statements other than statements of historical fact included on this announcement including, without limitation, statements regarding future plans and objectives of Optiscan or any of the other parties referred to herein, are forward-looking statements. Forward-looking statements can be identified by words such as 'anticipate', 'believe', 'could', 'estimate', 'expect', 'future', 'intend', 'may', 'opportunity', 'plan', 'potential', 'project', 'seek', 'will' and other similar words that involve risks and uncertainties. These statements are based on an assessment of present economic and operating conditions, and on assumptions regarding future events and actions that are expected to take place. Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of the Company, its directors and management of Optiscan that could cause actual results to differ from the results expressed or anticipated in these statements.*

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## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

OPTISCAN IMAGING LIMITED

**ABN**

81 077 771 987

**Quarter ended ("current quarter")**

30 SEPTEMBER 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	330	330
1.2 Payments for		
(a) research and development	(578)	(578)
(b) product manufacturing and operating costs	(261)	(261)
(c) advertising and marketing	(41)	(41)
(d) leased assets	-	-
(e) staff costs	(389)	(389)
(f) administration and corporate costs	(135)	(135)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	6	6
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	131	131
1.8 Other (provide details if material)	2	2
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(935)</b>	<b>(935)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	141	141
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payments for lease liabilities)	(50)	(50)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>91</b>	<b>91</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	8,442	8,442
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(935)	(935)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	91	91
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>7,598</b>	<b>7,598</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	7,598	8,442
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>7,598</b>	<b>8,442</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	186
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	<div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>N/A</p> </div>	

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(935)
8.2 Cash and cash equivalents at quarter end (item 4.6)	7,598
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	7,598
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	8.13
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
<p>Answer: N/A</p>	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
<p>Answer: N/A</p>	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
<p>Answer: N/A</p>	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	



## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

27 October 2021

Date: .....

The Board of Directors

Authorised by: .....  
(Name of body or officer authorising release – see note 4)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.